

Application No. 09/787,498
Amendment and Response dated September 28, 2005
Reply to Office Action mailed June 28, 2005

REMARKS

The Applicant and Applicant's attorney wish to thank the Examiner for the time spent reviewing the application and preparing the sixth Office Action. In the sixth Office Action, claims 1-28 and 30-54 were rejected. By this paper, claims 1-28, 30-37, 42-45, 50-51 and 54 have been amended and claims 38, 40, 46 – 48 have been cancelled. Applicant submits that claim amendments do not add new matter and entry thereof is respectfully requested. As a result, claims 1-28, 30-37, 39, 41-45, and 49-54 are pending and should be in condition for allowance. Reconsideration of the above-identified claims is now respectfully requested.

Objections to Drawings

In the sixth Office Action, the Examiner objected to the drawings under 37 CFR 1.83(a), with specific reference to the language "plurality of input ports" of claims 38 and 46 and "plurality of microchannels" of claims 40 and 48. By this paper, claims 38, 40, 46 and 48 have been cancelled. Therefore, the drawings should be in compliance with 37 CFR 1.83(a). As such, Applicant hereby requests that the objection to the drawings be removed.

Rejections Under 35 U.S.C. § 112

In the sixth Office Action, claims 1-28, 30-32 and 51-54 were rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement.

Regarding claims 1-21 and 51-53, the Examiner alleges that the claim limitation "a substantially planar major surface" was not adequately described in the original specification of the instant invention. By this paper, claims 1 and 51 have been amended to recite "a

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substantially planar first surface.” As such, Applicant submits that claims 1-21 and 51-53 are in compliance with the written description requirement.

Regarding claims 22-28, 30-32 and 54, the Examiner alleges that the claim limitation “a channel opening at an opposite distal end” was not adequately described in the original specification of the instant invention to show that Applicant possessed the invention at the time the application was filed. Applicant submits that such a limitation is adequately described in the original specification. According to the MPEP:

An objective standard for determining compliance with the written description requirement is, “does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed.” ... Whenever the issue arises, the fundamental factual inquiry is whether the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant was in possession of the invention as now claimed.... The subject matter of the claim need not be described literally (i.e., using the same terms or in *haec verba*) in order for the disclosure to satisfy the description requirement. MPEP §2163.02.

As is clearly shown in Figs. 2A-2B and described in the specification, the needle array 30 includes a plurality of microneedles 32 having a channel opening 34 at an opposite distal end. In particular, the specification recites “[t]he microneedles 32 each terminate at a needle tip 33 with a channel opening 34 therein” (p. 6, ll. 3-4), and “[o]ne or more input ports 37 and output ports 39 can be optionally formed in microneedles 32 to increase fluid input and output flow.” (p. 6, ll. 7-9). As clearly shown in Figs. 2A-2B, the input ports 37 are located at a proximal end of the microneedles 32 and the output ports 39 are located at an opposite distal end of the microneedles 32. Further, the channel openings 34 are illustrated as being adjacent the output ports 39. Thus, the specification supports the limitation of a channel opening, and supports to the limitation of a channel opening at an opposite distal end, as articulated in claim 22. As such, one skilled in the art would conclude that the specification, particularly the detailed description and associated

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figures, conveys with reasonable clarity that Applicant was in possession of the claimed invention as of the filing date. Therefore, claims 22-28, 30-32 and 54 are in compliance with 35 U.S.C. §112, ¶1.

In the sixth Office Action, claims 40 and 48 were rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. By this paper, claims 40 and 48 have been cancelled. Thus, the rejection to claims 40 and 48 under 35 U.S.C. § 112, first paragraph is now moot and should be removed. As such, Applicant respectfully requests reconsideration and removal of the rejections under 35 U.S.C. § 112 to the above identified claims.

Rejections Under 35 U.S.C. § 102

Claims 1-5, 8-11, 13-18, 20, 21, 33-37 and 43-45 are rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 3,964,482 to Gerstel et al. (the "Gerstel" patent). Applicant submits that Gerstel fails to disclose the limitations recited with respect to each of claims 1, 33 and 43.

Gerstel does not disclose a microneedle array device, as defined in Claim 1, comprising a substrate having a substantially planar first surface and an edge adjacent said substantially planar first surface, and a plurality of hollow non-silicon microneedles positioned on said substantially planar first surface of said substrate, wherein said hollow non-silicon microneedles extend beyond said edge of said substrate and extend in a direction substantially parallel to said substantially planar first surface, as articulated in Claim 1.

Rather, as depicted in the figures, Gerstel discloses one surface 14 and a second surface, designated by the Examiner as 16, that appears to be substantially perpendicular to the one

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surface 14. As clearly shown by the figures, the projections 12 are located on the one surface 14, not on the second surface 16, and the projections 12 extend perpendicular to the one surface 14. Further, the detailed description of Gerstel discloses "a plurality of projections 12 extending outwardly from one surface 14" (see col. 4, ll. 24-25). As such, the projections 12 of Gerstel do not extend in a direction substantially parallel to the one surface 14 on which the projections 12 are located. Therefore, because Gerstel does not disclose all the limitations recited with respect to Claim 1, Applicants request that the rejection under 35 U.S.C. § 102(b) be removed from Claim 1.

Likewise, Gerstel fails to disclose a microneedle device, as defined in claim 33, comprising a substrate having a substantially planar first surface and an edge adjacent said substantially planar first surface, and a single hollow non-silicon microneedle positioned on said substantially planar first surface of said substrate, wherein a distal end of said hollow non-silicon microneedle extends beyond said edge of said substrate, and wherein said hollow non-silicon microneedle extends in a direction substantially parallel to said substantially planar first surface, as recited in claim 33.

Similarly, Gerstel does not disclose a microneedle device, as defined in claim 43, comprising a single hollow elongated shaft, and at least one input port at the proximal end of said hollow elongated shaft and a plurality of output ports at the distal end, as recited in claim 43.

Therefore, Applicant requests removal of the rejection under 35 U.S.C. §102(b) to claims 1-5, 8-11, 13-18, 20, 21, 33-37 and 43-45. Reconsideration and allowance of the identified claims is hereby respectfully requested.

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Claims 51-53 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 4,728,392 to Miura et al. Applicants submit that Miura does not disclose the limitations recited with respect to Claim 51.

The Examiner states in the sixth Office Action, with regards to Miura, that "[t]here are two surfaces: a length and thickness, both of which can be interpreted to be a 'major surface.'" (p. 12, emphasis added). Claim 51 has been amended for clarity or to more particularly define Applicant's invention, to require providing a substrate with a substantially planar first surface, wherein one or more microneedles are formed on said substantially planar first surface and extend in a direction substantially parallel to said substantially planar first surface.

As such, Miura fails to disclose a method of fabricating a microneedle comprising the steps of providing a substrate with a substantially planar first surface, depositing a metal material on said substantially planar first surface to form one or more bottom walls for one or more microneedles, wherein said one or more microneedles are formed on said substantially planar first surface of said substrate and extend in a direction substantially parallel to said substantially planar first surface, as articulated in Claim 51.

Accordingly, Miura does not disclose all the limitations recited with respect to Claim 51. As such, Applicant requests that the rejection under 35 U.S.C. § 102(b) be removed from Claims 51-53.

Rejections Under 35 U.S.C. § 102 and 35 U.S.C. § 103

Claims 22-28 and 30-32 are rejected under 35 U.S.C. 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as being obvious over U.S. Patent No. 3,964,482 to Gerstel et al.

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To establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. *See* M.P.E.P. § 2143.

Applicants submit that Gerstel does not disclose, teach or suggest all the limitations recited with respect to Claim 22, particularly as amended. Gerstel does not disclose, teach or suggest a microneedle array device comprising a plurality of hollow non-silicon microneedles having a microchannel therethrough providing communication between at least one input port at a proximal end of each of said hollow non-silicon microneedles and at least one output port and a channel opening at a distal end of each of said hollow non-silicon microneedles, as articulated in Claim 22. As such, Applicants submit that the rejection to claims 22-28 and 30-32 under 35 U.S.C. § 102/103 should be removed.

Rejections under 35 U.S.C. § 103

Claims 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gerstel in view of U.S. Patent No. 5,406,573 to Ozbay et al. Claims 12, 19, 38-42, 46-50 and 54 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Gerstel, as applied to claims 1, 22, 33 and 43.

Claims 6, 7, 12, 19, 38-42, 46-50 and 54 depend from an allowable base claim and incorporate all the limitations of their respective base claim therein. As such, the rejection to claims 6, 7, 12, 19, 38-42, 46-50 and 54 under 35 U.S.C. 103 should be removed.

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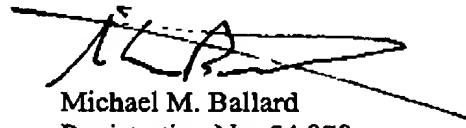
Conclusion

By this paper pending claims 1-28, 30-37, 42-45, 50-51 and 54 have been amended for the sake of clarity or to more clearly point out the novel aspects of Applicant's invention, and claims 38, 40 and 46-48 have been cancelled. Claims 2-21, 23-28, 30-32, 34-37, 39, 41-42, 44-45, 49-50 and 52-54 depend from an allowable base claim, incorporating all the limitations of their respective base claim therein. As a result, claims 1-28, 30-37, 39, 41-45 and 49-54 are pending and should be in condition for allowance. Reconsideration and allowance of the above-identified claims is now respectfully requested.

In the event that the Examiner finds remaining impediment to a prompt allowance of this application that may be clarified through a telephone interview, the Examiner is requested to contact the undersigned attorney.

Dated this 28 day of September 2005.

Respectfully submitted,



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